## CLAIMS

What is claimed is:

1. A process for preparing polymer microspheres comprising a polymer and a peptide, which comprises the steps of:

neutralizing a peptide salt with a weak base in an aqueous medium wherein said medium comprises a suspension of hydroxyapatite or a solution of calcium mono-hydrogen phosphate to form a precipitate;

isolating the precipitate;

suspending the precipitate in an organic solvent, which comprises a polymer dissolved therein to form a suspension;

dispersing the suspension in an aqueous solution of a surfactant; and

evaporating the organic solvent to isolate the polymer microspheres.

2. A process according to claim 1, comprising the additional step of dissolving the peptide salt in a minimum of water before neutralizing the peptide salt.

3. A process according to claim 2, wherein the surfactant is one or more of sodium oleate, sodium stearate, sodium laurylsulphate, a poly(oxyethylene) sorbitan fatty acid ester, polyvinylpyrrolidine, polyvinyl alcohol, carboxymethyl cellulose, lecithin, gelatin or hyaluronic acid.

4. A process according to claim 3, wherein the surfactant is polyvinyl alcohol and the pH of the polyvinyl alcohol is 6.5-7.5.

5. A process according to claim 4, wherein the pH of the polyvinyl alcohol is 6.9-7.1.

6. A process according to claim 5, wherein the organic solvent is dichloromethane, chloroform or ethyl acetate.

7. A process according to claim 6, wherein the organic solvent is dichloromethane and the concentration of the polymer in the organic solvent is 0.5% to 30% by weight.

8. A process according to claim 7, wherein the concentration of the polymer in dichloromethane is 0.5% to 10% by weight.

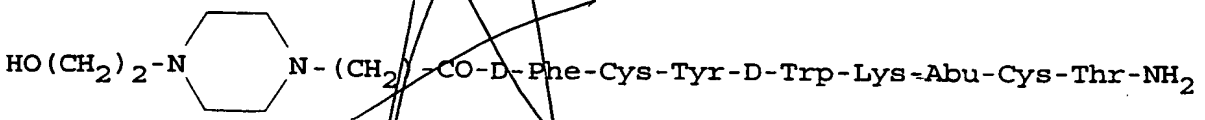
9. A process according to claim 8, wherein the peptide is growth hormone releasing peptide, luteinizing hormone-releasing hormone, somatostatin, bombesin, gastrin releasing peptide, calcitonin, bradykinin,

galanin, melanocyte stimulating hormone, growth hormone releasing factor, amylin, tachykinins, secretin, parathyroid hormone, enkephalin, endothelin, calcitonin gene releasing peptide, neuromedins, parathyroid hormone related protein, glucagon, neurotensin, adrenocorticothrophic hormone, peptide YY, glucagon releasing peptide, vasoactive intestinal peptide, pituitary adenylate cyclase activating peptide, motilin, substance P, neuropeptide Y, or TSH or an analogue or a fragment thereof or a pharmaceutically acceptable salt thereof.

10. A process according to claim 9, wherein the peptide is the LHRH analogue of the formula pyroGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-$NH_2$.

11. A process according to claim 10, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

12. A process according to claim 9, wherein the peptide is selected from the group of somatostatin analogues consisting of H-D-β-Nal-Cys-Tyr-D-Trp-Lys-Thr-Cys-Thr-$NH_2$,

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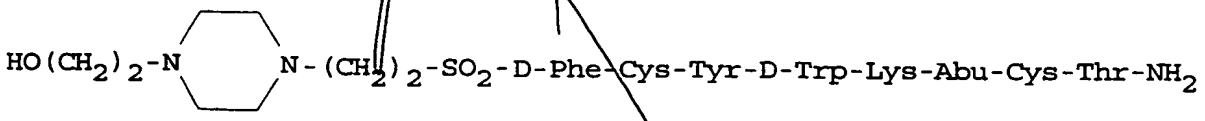


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13. A process according to claim 12, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

14. A polymer microsphere made according to the process of claim 1.

15. A polymer microsphere made according to the process of claim 11.

16. A polymer microsphere made according to the process of claim 13

17. A process for preparing polymer microspheres and nanospheres comprising a polymer and a peptide, which comprises the steps of:

dissolving a salt of a peptide complexed with an anionically or cationically functionalized biodegradable polyester in an organic solvent to form a solution;

dispersing the solution in an aqueous solution of a surfactant; and

evaporating the organic solvent to isolate the polymer microspheres and nanospheres.

18. A process according to claim 17, wherein the anionically functionalized biodegradable polyester is functionalized with an anionic moiety selected from the group consisting of carboxylate, phosphate and sulfate and the cationically functionalized biodegradable polyester is functionalized with a cationic moiety selected from the group consisting of amino, amidino, guadino, ammonium, cyclic amino groups and nucleic acid bases.

19. A process according to claim 18 wherein the organic solvent is dichloromethane, chloroform or ethyl acetate.

20. A process according to claim 19, wherein the organic solvent is dichloromethane and the concentration of the polymer in the dichloromethane is 0.5% to 30% by weight.

21. A process according to claim 20, wherein the concentration of the polymer in the dichloromethane is 0.5% to 10% by weight.

22. A process according to claim 21, wherein the surfactant is one or more of sodium oleate, sodium stearate, sodium laurylsulphate, a poly(oxyethylene) sorbitan fatty acid ester, polyvinylpyrrolidine, polyvinyl alcohol, carboxymethyl cellulose, lecithin, gelatin or hyaluronic acid.

23. A process according to claim 22, wherein the surfactant is polyvinyl alcohol and the pH of polyvinyl alcohol is 6.5-7.5.

24. A process according to claim 23, wherein the pH of polyvinyl alcohol is 6.9-7.1.

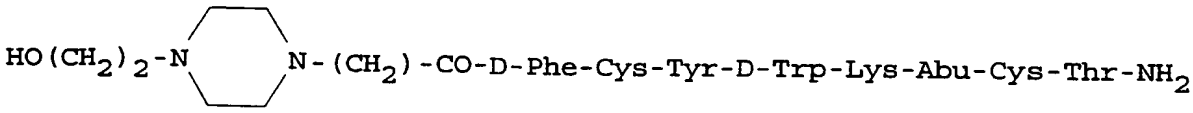
25. A process according to claim 24, wherein the peptide is growth hormone releasing peptide, luteinizing hormone-releasing hormone, somatostatin, bombesin, gastrin releasing peptide, calcitonin, bradykinin, galanin, melanocyte stimulating hormone, growth hormone releasing factor, amylin, tachykinins, secretin, parathyroid hormone, enkephalin, endothelin, calcitonin gene releasing peptide, neuromedins, parathyroid hormone related protein, glucagon, neurotensin, adrenocorticothrophic hormone, peptide YY,

glucagon releasing peptide, vasoactive intestinal peptide, pituitary adenylate cyclase activating peptide, motilin, substance P, neuropeptide Y, or TSH or an analogue or a fragment thereof or a pharmaceutically acceptable salt thereof.

26. A process according to claim 25, wherein the peptide is the LHRH analogue of the formula pyroGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-$NH_2$.

27. A process according to claim 26, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

28. A process according to claim 25, wherein the peptide is selected from the group of somatostatin analogues consisting of H-D-β-Nal-Cys-Tyr-D-Trp-Lys-Thr-Cys-Thr-$NH_2$,

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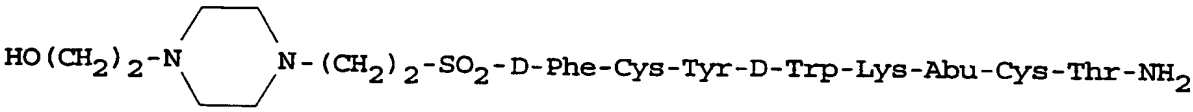


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29. A process according to claim 28, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

30. A polymer microsphere made according to the process of claim 17.

31. A polymer microsphere made according to the process of claim 27.

32. A polymer microsphere made according to the process of claim 29.

33. A process for preparing polymer microspheres and nanospheres comprising a polymer and a peptide, which comprises the steps of:

dissolving a salt of a peptide complexed with an anionic counterion in an organic solvent which is selected from the group consisting of dichloromethane, chloroform and ethyl acetate to form a solution;

dispersing the solution in a surfactant; and

evaporating the organic solvent to isolate the polymer microspheres and nanospheres.

34. A process according to claim 33, wherein the anionic counterion is dioctylsulfosuccinate, dodecylsulfate, tannate, pamoate, alginate, cyclodextrin sulfate, cyclodextrin phosphate, bisphosphonate or inisitol phosphate.

35. A process according to claim 34 wherein the organic solvent is dichloromethane.

36. A process according to claim 35, wherein the concentration of the polymer in dichloromethane is 0.5% to 30% by weight.

37. A process according to claim 36, wherein the concentration of the polymer in dichloromethane is 0.5% to 10% by weight.

38. A process according to claim 37, wherein the surfactant is one or more of sodium oleate, sodium stearate, sodium laurylsulphate, a poly(oxyethylene) sorbitan fatty acid ester, polyvinylpyrrolidine, polyvinyl alcohol, carboxymethyl cellulose, lecithin, gelatin or hyaluronic acid.

39. A process according to claim 38, wherein the surfactant is polyvinyl alcohol and the pH of polyvinyl alcohol is 6.5-7.5.

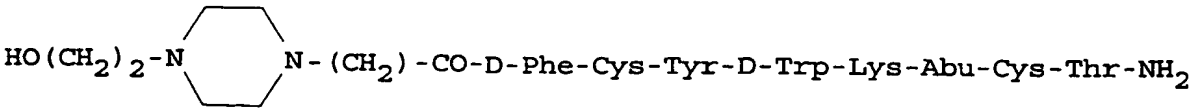
40. A process according to claim 39, wherein the pH of polyvinyl alcohol is 6.9-7.1.

41. A process according to claim 40, wherein the peptide is growth hormone releasing peptide, luteinizing hormone-releasing hormone, somatostatin, bombesin, gastrin releasing peptide, calcitonin, bradykinin, galanin, melanocyte stimulating hormone, growth hormone releasing factor, amylin, tachykinins, secretin, parathyroid hormone, enkephalin, endothelin, calcitonin gene releasing peptide, neuromedins, parathyroid hormone related protein, glucagon, neurotensin, adrenocorticothrophic hormone, peptide YY, glucagon releasing peptide, vasoactive intestinal peptide, pituitary adenylate cyclase activating peptide, motilin, substance P, neuropeptide Y, or TSH or an analogue or a fragment thereof or a pharmaceutically acceptable salt thereof.

42. A process according to claim 41, wherein the peptide is the LHRH analogue of the formula pyroGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-$NH_2$.

43. A process according to claim 42, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

44. A process according to claim 41, wherein the peptide is selected from the group of somatostatin analogues consisting of H-D-β-Nal-Cys-Tyr-D-Trp-Lys-Thr-Cys-Thr-$NH_2$,



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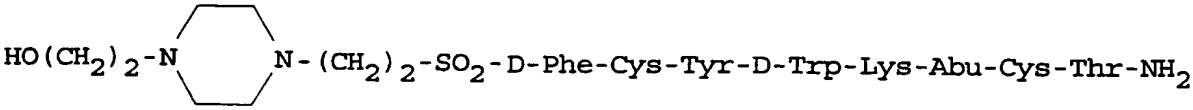

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45. A process according to claim 44, wherein the polymer is polylactide-co-glycolide, polycaprolactone or polyanhydride or a copolymer or blends thereof.

46. A polymer microsphere made according to the process of claim 33.

47. A polymer microsphere made according to the process of claim 43.

48. A polymer microsphere made according to the process of claim 45.